

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

FRESENIUS MEDICAL CARE
HOLDINGS, INC., et al.,

No. C 03-1431 SBA

Plaintiffs,

ORDER

v.

[Docket No. 493]

BAXTER INTERNATIONAL, INC., et al.,

Defendants.

This matter comes before the Court on Defendants Baxter International, Inc. and Baxter Healthcare Corporation's (collectively, "Defendants" or "Baxter") Motion to Strike PTO Documents as Exhibits to Fresenius' Motion for Summary Judgment of the '434 and '131 Patents Pursuant to Rule 802. Having read and considered the arguments presented by the parties in the papers submitted to the Court, the Court finds this matter appropriate for resolution without a hearing. The Court hereby DENIES WITHOUT PREJUDICE Baxter's Motion to Strike PTO Documents as Exhibits to Fresenius' Motion for Summary Judgment of the '434 and '131 Patents Pursuant to Rule 802 [Docket No. 493].

BACKGROUND

Plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical Care Holdings, Inc. (collectively "Fresenius") initiated this patent suit on April 4, 2003 by filing a Complaint for Declaratory Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter International, Inc. and Baxter Healthcare Corporation (collectively "Baxter"). Fresenius cited five patents in its complaint: (1) U.S. Patent No. 5,247,434 ("434 Patent"); (2) U.S. Patent No. 5,326,476 ("476 Patent"); (3) U.S. Patent No. 6,284,131 B1 ("131 Patent"); (4) U.S. Patent No.

1 5,486,286 ("286 Patent"); and (5) U.S. Patent No. 5,744,027 ("027 Patent") (collectively
2 "patents-in-suit").

3 On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K
4 hemodialysis machines infringe four of the five patents. On October 20, 2003, Baxter amended its
5 answer and counterclaims to assert infringement of the '286 Patent.

6 On February 21, 2006, Fresenius filed a Motion for Summary Judgment seeking partial summary
7 judgment that the asserted claims of the '434 and '131 patents are invalid as obvious under U.S.C. §
8 103(a); that the asserted claims of the '131 patent are invalid as anticipated under 35 U.S.C. § 102(b);
9 and that certain asserted claims of the patents-in-suit are invalid for failure to satisfy the enablement and
10 best mode requirements of 35 U.S.C. § 112.

11 Also on February 21, 2006, Fresenius filed a Motion for Summary Judgment seeking partial
12 summary judgment that claim 5 of the '476 Patent and claim 11 of the '027 Patent are invalid as obvious
13 under 35 U.S.C. § 103(a); that claim 7 of the '476 Patent and claims 1, 2, 4, 6-8, 10, and 12-16 of the
14 '027 Patent are invalid as anticipated under 35 U.S.C. § 102(b); and that claim 5 of the '476 Patent is
15 invalid for failure to satisfy the definiteness and enablement requirements of 35 U.S.C. § 112.

16 On March 7, 2006, Baxter filed a Motion for Partial Summary Judgment of Validity seeking
17 judgment that the asserted claims of the '434 and '131 patents are not invalid under 35 U.S.C. § 102 for
18 anticipation, and that certain asserted claims of the patents-in-suit do not violate the best mode and/or
19 enablement requirements of 35 U.S.C. § 112.

20 On March 21, 2006, Baxter filed the instant Motion to Strike PTO Documents as Exhibits to
21 Fresenius' Motion for Summary Judgment of the '434 and '131 Patents Pursuant to Rule 802.

22 ANALYSIS

23 In Baxter's Motion to Strike PTO Documents as Exhibits to Fresenius' Motion for Summary
24 Judgment of the '434 and '131 Patents,¹ there are four documents that Baxter seeks to strike: (1) an
25 August 2003 opinion of the U.S. Patent and Trademark Office's ("PTO") Board of Patent Appeals and
26 Interferences concerning U.S. Patent Application No. 09/711,240 (the "Board Opinion"); (2) a June
27

28 ¹Fresenius' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent
Nos. 5,247,434 and 6,284,131 is cited to herein as "Fresenius MSJ I."

2005 Office Action by a PTO Examiner concerning U.S. Patent Application No. 10/461,322 (the "June 2005 Office Action"); (3) a November 2005 PTO order granting reexamination of the '131 Patent (the "November 2005 Reexamination Order"); and (4) a January 2006 PTO order granting reexamination of the '434 Patent (the "January 2006 Reexamination Order"). See McClenahan Decl. ISO Fresenius MSJ I at Exs. 1, 2, 21, and 22. Baxter moves to strike these exhibits on the grounds that the documents are inadmissible hearsay and do not fall within the public records exception found at Federal Rule of Evidence 803(8).²

"Hearsay" is a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted. Fed. R. Evid. 801. In general, hearsay is inadmissible. Fed. R. Evid. 802. However, Rule 803(8) provides an exception to the hearsay exclusion rule known as the "public records" exception. The "public records" exception states that the following documents are admissible, even if otherwise considered hearsay:

Records, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the office or agency, or (B) matters observed pursuant to duty imposed by law as to which matters there was a duty to report, excluding, however, in criminal cases matters observed by police officers and other law enforcement personnel, or (C) in civil actions and proceedings and against the Government in criminal cases, factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness.

Fed. R. Evid. 803(8). Factually based conclusions or opinions are also covered by Rule 803(8)(C). *Beech Aircraft v. Rainey*, 488 U.S. 153, 170 (1988).

With respect to public records, the presumption is one of trustworthiness, and the burden of establishing untrustworthiness falls on the opponent of the evidence. See *Keith v. Volpe*, 858 F.2d 467, 481 (9th Cir. 1988). "A party opposing the introduction of a public record bears the burden of coming forward with enough negative factors to persuade a court that a report should not be admitted." *Johnson v. City of Pleasanton*, 982 F.2d 350, 352 (9th Cir. 1992).

²Alternatively, Baxter asks the Court to strike the exhibits pursuant to Federal Rule of Evidence 403 on the grounds that their prejudicial effect outweighs any probative value. However, the Rule 403 argument is not clearly set forth as a basis for Baxter's Motion but, rather, is included in a footnote to the argument section of the Motion. The Court notes that Fresenius has not provided any argument in response to Baxter's assertion that the documents should be excluded under Rule 403, presumably because Baxter fails to expound on its Rule 403 argument in its Motion.

1 The United States Patent and Trademark Office ("PTO") is an agency of the United States,
2 within the Department of Commerce, and thus falls squarely within the "public offices or agencies"
3 requirement of Rule 803(8). However, Baxter argues that the November 2005 Reexamination Order
4 and the January 2006 Reexamination Order do not fall within the public records exception because they
5 are not final. Baxter further asserts that the lack of finality associated with the reexamination orders,
6 coupled with the fact that the reexamination orders are directed to the question of patentability, rather
7 than invalidity, demonstrates that the documents lack trustworthiness. With respect to the June 2005
8 Office Action, Baxter also asserts that the decision is non-final and "untrustworthy" due to the fact that
9 the one claim rejected by the PTO in the action was not a claim from the '434 or '131 Patents and
10 because the evidentiary standard in PTO actions differs significantly from the evidentiary standard
11 employed in litigation. Finally, Baxter argues that the August 2003 Board Opinion is similarly non-final
12 and untrustworthy due to the fact that Baxter decided to prosecute a continuation application and
13 because the PTO proceedings employed a lower evidentiary burden.

14 As Fresenius points out, Baxter does not cite a single case in support of its Motion where a court
15 has excluded PTO documents as inadmissible hearsay. To the contrary, courts regularly consider such
16 documents when construing claims for the purposes of infringement and validity analyses. *See, e.g.,*
17 *Terlep v. Brinkmann Corp.*, 418 F.3d 1368, 1382 (Fed. Cir. 2005); *Biagro W. Sales, Inc. v. Grow More,*
18 *Inc.*, 423 F.3d 1296, 1303 (Fed. Cir. 2005) (acknowledging that a statement made by an examiner during
19 reexamination could show how a person skilled in the art would interpret claim language). Further, the
20 primary cases Baxter relies upon in support of its Motion do not pertain to the PTO and are inapposite.³
21 *See Rambus, Inc. v. Infineon Techs. AG*, 222 F.R.D. 101 (E.D. Va. 2004) (excluding an Administrative
22 Law Judge's initial decision after holding that the decision was not an agency finding of fact and after
23 noting that the party moving to strike had identified numerous factors indicating that the document
24 lacked trustworthiness); *City of New York v. Pullman Inc.*, 662 F.2d 910 (2d Cir. 1981) (excluding an

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26 ³The one relevant Federal Circuit decision that *Baxter* does rely upon does not support its
27 argument that PTO documents should be excluded as hearsay. In fact, in *Quad Enviro. Techs. Corp.*
28 *v. Union Sanitary Dist.*, 946 F.2d 870 (Fed. Cir. 1999), the Federal Circuit expressly noted that courts
may "take cognizance of, and benefit from, the proceedings before the patent examiner" – *even*
reexamination proceedings. *Id.* at 876.

1 "interim" staff report subject to internal revision and review and thus not a final agency report or
2 finding).

3 Moreover, as Fresenius has aptly demonstrated, Baxter has not met its burden in showing that
4 any of the documents lack "finality" in the sense that is relevant under Rule 803(8). For example, with
5 respect to the August 2003 Board Opinion, the decision became "final" on or about December 8, 2003,
6 when the time period for seeking court review of the decision expired and the Patent Office sent a
7 Notice of Abandonment. *See* McClenahan Decl. ISO Mot. to Strike at Ex. 16; *see also* 17 C.F.R. §
8 1.198 ("When a decision by the Board of Patent Appeals and Interferences on appeal has become final
9 for judicial review, prosecution of the proceeding before the primary examiner will not be reopened or
10 reconsidered by the primary examiner except under the provisions of § 1.114 or § 41.50 of this title
11 without the written authority of the Director, and then only for the consideration of matters not already
12 adjudicated, sufficient cause being shown."). Similarly, with respect to the June 2005 Office Action,
13 although it is labeled "non-final" as far as the PTO proceedings are concerned, and although Baxter may
14 be entitled to appeal or respond to the decision, this does not render it an "interim" report within the
15 meaning of the *City of New York*. Finally, with respect to the reexamination orders, it is clear that the
16 determination that a substantial new question of patentability exists is a final decision from the agency
17 on that particular question. *See* MPEP § 2209.

18 Baxter's argument regarding the lack of trustworthiness of the PTO decisions is similarly
19 unavailing. First, and most significantly, it cannot be overlooked that, when it suits it, Baxter relies on
20 numerous PTO documents – for the truth of the matters asserted therein– throughout its summary
21 judgment briefing. For example, in its Motion for Partial Summary Judgment, Baxter states that
22 "[d]uring the prosecution of the '434 Patent, the applicants summarized an interview with the examiner
23 where he 'deemed enabling the specification.'" *See* Baxter MSJ at 22 (citing Abernathy Decl. at Ex. 24).
24 Baxter also repeatedly refers to the fact that the decisions of the patent examiner are given great
25 deference. Additionally, in its Opposition to Fresenius' Motion for Summary Judgment of Invalidity
26 of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131, Baxter cites a PTO Examiner's
27 Notice of Allowability and states: "The Examiner's Reasons for Allowance show that he extensively
28 considered the teachings of Kerns and Rubalcaba." *See* Opp. to MSJ I at 5. In fact, the Notice of

1 Allowability is attached as an exhibit supporting Baxter's opposition brief. Additionally, although
2 Baxter argues that the PTO's decisions are "untrustworthy" due to the "quality of procedural devices
3 available" during the proceedings, Baxter cannot deny the fact that the same procedural devices were
4 employed during the proceedings when the examiners decided to allow the asserted claims.
5 Accordingly, Baxter has not come forward with enough "negative" factors showing that the PTO
6 documents are untrustworthy and therefore excludable hearsay.

7 Although Baxter's Motion falters under the hearsay rule, however, its Reply brief does cite
8 persuasive authorities indicating that it may be appropriate to exclude the reexamination orders at trial
9 if their probative value is outweighed by their potential to prejudice the jury. For example, in *Hoechst*
10 *v. BP Chemicals Ltd.*, 78 F.3d 1575, 1584 (Fed. Cir. 1996), the Federal Circuit noted that the "grant by
11 the examiner of a request for reexamination is not probative of unpatentability" and "does not establish
12 a likelihood of invalidity." *Id.* The Federal Circuit further noted that, in 1994, 89% of reexamination
13 requests were granted but only 5.6% of the reexamined patents were rejected. *Id.* Relying on *Hoechst*,
14 the United States District Court for the Northern District of Illinois, when faced with this precise issue,
15 decided to exclude certain reexamination orders relating to the patents-in-suit after finding that "telling
16 the jury that the patent has been called into question by the Patent Office [might] significantly influence
17 the jury's application of the presumption of validity and significantly prejudice [the patent holder]."
18 *Amphenol T&M Antennas, Inc. v. Centurion Int'l, Inc.*, 2002 U.S. Dist. LEXIS 822 *5 (N.D. Ill. 2002).

19 However, as noted above, Baxter's Rule 403 argument was not clearly asserted as a basis for its
20 Motion and, by including this argument in its Reply brief, Baxter deprived Fresenius of a meaningful
21 opportunity to respond. Further, the Court finds that it may be possible that any prejudicial effect on
22 the jury could be alleviated by the appropriate jury instructions. As such, the Court has no basis to
23 conclude at this juncture that the documents are not admissible. The Court therefore DENIES Baxter's
24 Motion to Strike WITH PREJUDICE with respect to Rule 802 but WITHOUT PREJUDICE with
25 respect to Rule 403. For the purposes of the instant summary judgment motions, all of the exhibits have
26 been considered. However, since Fresenius' arguments do not necessarily rely on the reexamination
27 orders, the relevant analysis does not turn on their inclusion. Further, although the August 2003 Office
28 Action and the June 2005 Office Action have also been considered, the ultimate result is that – even if

1 included – they are not sufficient to carry Fresenius' burden of proof. Thus, Baxter has not been
2 prejudiced by the Court's consideration of any of the exhibits at this stage in the proceedings. Further,
3 while the Court is sensitive to the fact Baxter may have a viable argument that the documents should
4 be excluded before presented to a jury, Fresenius may also have viable arguments that the appropriate
5 jury instructions could sufficiently take care of any prejudicial effect. Therefore, if Baxter still wishes
6 to pursue a motion to exclude, Baxter is hereby granted leave to renew its Rule 403 argument in a
7 motion in limine so the Court can benefit from adequate briefing on this issue from *both* sides before
8 making its final determination regarding the admissibility of the documents.

9 **CONCLUSION**

10 IT IS HEREBY ORDERED THAT Baxter's Motion to Strike [Docket No. 493] is DENIED
11 WITHOUT PREJUDICE, to the extent that it relies on Federal Rule of Evidence 403, but DENIED
12 WITH PREJUDICE to the extent that it relies on Federal Rule of Evidence 802.

13 IT IS SO ORDERED.

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15 Dated: 5/15/06

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17 SAUNDRA BROWN ARMSTRONG
18 United States District Judge
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